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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|----------------|----------------------|-------------------------|------------------|
| 10/009,453 | 11/05/2001 | Bernd Fabry | H 4132 PCT/US | 1938 |
| 23657 75 | 590 05/16/2005 | | EXAMINER | |
| COGNIS CORPORATION | | | ЛANG, SHAOЛA A | |
| PATENT DEPARTMENT 300 BROOKSIDE AVENUE | | | ART UNIT | PAPER NUMBER |
| AMBLER, PA | 19002 | | 1617 | |
| | • | | DATE MAILED: 05/16/2005 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | |
|---|--|-----------------------------|--|--|--|--|
| | 10/009,453 | FABRY ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Shaojia A. Jiang | 1617 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on <u>17 February 2005</u> . | | | | | | |
| 2a)⊠ This action is FINAL . 2b)☐ This | action is non-final. | | | | | |
| Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4) Claim(s) 9,10,12-16 and 18-24 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 9,10,12-16 and 18-24 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Ex | • | • • | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4) Interview Summary Paper No(s)/Mail Da | ite | | | | |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date | 5) Notice of Informal P 6) Other: | atent Application (PTO-152) | | | | |

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DETAILED ACTION

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This Office Action is in response to Applicant's response (remarks/Arguments) filed February 17, 2005 wherein no claims are amended, cancelled, or newly submitted.

Currently, claims 9-10, 12-16, and 18-24 are pending in this application and under examination on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-10, 15-16, and 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Selvaraj et al. (WO 97/13503) for same reasons of record stated in the Office Action dated November 18, 2004, and reiterated in full below.

Selvaraj et al. discloses a composition comprising

- (a) an active ingredient such as a cosmetically-active agent, or a pharmaceutically-active or therapeutic agent; and
- b) nanoparticles having a mean diameter within the instant range such as less than 250 nm (see page 5 line 28) or about 90 nm (see page 7 line 21) or about 100 nm (see page 9 line 19-20 and page 12 line 20-21), comprising metal soap such as calcium stearate (see page 6 line 19), a protective colloid such as a protein which is gelatin(see page 6 line 3 and page 7 line 4); carbohydrate such as starch and gum arabic (see

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page 6 line 14-15), and an emulsifier and mixtures thereof (see page 6-7), and the process for making the composition therein, in particular the method or process for making the nanoparticles therein. See also abstract, page 4 line 21 to page 5; page 17; claims 1-27 therein.

Selvaraj et al. also discloses that nanoparticles are present in the composition in an amount about 10% or 15% wt or at least 10% wt (see page 11 line 27 to page 12 line 1). Selvaraj et al. further teaches that process parameters such as size of nanoparticles and the weight percentage of nanoparticles in the composition, can be determined by one of ordinary skill using the teaching of Selvaraj et al. in WO 97/13503 (see page 10 line 1-7).

Thus, the disclosure of Selvaraj et al. anticipates claims 9-10, 15-16, and 21-24.

Response to Argument

Applicant's arguments filed February 17, 2005 with respect to this rejection of claims 9-10, 15-16, and 21-24 made under 35 U.S.C. 102(b) of record in the previous Office have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art as further discussed below.

Applicant asserts that Selvaraj et al. neither teaches nor suggest nanoparticulate metal soaps coated with a protective colloid and emulsifier and mixtures thereof.

Applicant also acknowledges that Selvafaj et al. discloses active pharmaceutical compositions which a matrix, which matrix material can conform to a metal soap.

Applicant also argues that Selvafaj et al. disclose the different function of the matrix material from the claimed composition herein.

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Applicant's arguments are not persuasive, since, first, the instant claims are directed to a composition comprising two ingredients (a) and (b); the composition of Selvafaj et al. clearly comprises the same two ingredients (a) and (b) wherein the matrix material clearly reads on the metal soap nanoparticles claimed herein. Second, the different function or the "intended use" of the matrix material composition of Selvafaj et al. would not be limited the composition of Selvafaj et al. to anticipate the claimed composition, since it is well settled that "intended use" of a composition or product will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same ingredients in an effective amount as the instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 102(b). Therefore, said rejection is adhered to.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12-14 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Selvaraj et al. (WO 97/13503) for same reasons of record stated in the Office Action dated November 18, 2004, and reiterated in full below.

The same disclosure of Selvaraj et al. has been discussed in the 102(b) rejection above.

The cited prior art does not expressly disclose that the amount of the nanoparticles in the composition therein is from 0.1 to 5.0% or 0.5 to 3 % or 1 to 2% by weight.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to determine the amount of the nanoparticles in the composition therein to be from 0.1 to 5.0% or 0.5 to 3 % or 1 to 2% by weight.

One having ordinary skill in the art at the time the invention was made would have been motivated to determine the amount of the nanoparticles in the composition therein to be from 0.1 to 5.0% or 0.5 to 3 % or 1 to 2% by weight, since the amount of the nanoparticles in the composition of Selvaraj et al. is known to be about 10% or 15% wt. Selvaraj et al. further teaches that process parameters such as the weight percentage of nanoparticles in the composition and size of nanoparticles, can be determined by one of ordinary skill using the teaching of Selvaraj et al. in WO 97/13503.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

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Thus the claimed invention as a whole is seen to be prima facie obvious over the teachings of the prior art.

Applicant's same arguments as the 102(b) rejection with respect to this rejection made under 35 U.S.C. 103(a) of record in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art as discussed above.

Double Patenting

The <u>nonstatutory double patenting rejection</u> is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15-16 are rejected under the judicially created doctrine of obviousnesstype double patenting as being unpatentable over claim 9 of U.S. Patent No. 6,716,438 for same reasons of record stated in the Office Action dated November 18, 2004.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent, i.e. claim 9, is drawn to a method of making a

composition comprising the same ingredients with the same method or process steps as claimed herein, such as nanoparticles with size, 5-500 nm, including alkali metal soaps of fatty acids (see the disclosure at col.6 line 44-56).

Thus, the instant claims 15-16 are seen to anticipate claim 9 of U.S. Patent No. 6,716,438.

Response to Argument

Applicant's arguments filed February 17, 2005 with respect to this obviousnesstype double patenting rejection of record in the previous Office have been fully considered but they are not deemed persuasive as further discussed below.

Applicant asserts that "there is no relation between the use of nanoparticles of an antimicrobial material and the introduction of nanoparticles of a metal soap that are coated with protective colloid or the emulsifier". However, as discussed above, the specification of US 6,716,438 clearly discloses that the antimicrobial agent particles that are coated with one or more emulsifiers, or protective colloids, may contain alkali metal soaps of fatty acids (see the disclosure at col.6 line 44-56).

Thus, the relation between the use of nanoparticles of an antimicrobial material and the introduction of nanoparticles of a metal soap that are coated with protective colloid or the emulsifier is seen.

In view of the rejections to the pending claims set forth above, no claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Anna Jiang, Ph.D.

Primary Examiner

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May 10, 2005